HB 4110-A4
(LC 159)
2/14/14 (LHF/ps)

PROPOSED AMENDMENTS TO
A-ENGROSSED HOUSE BILL 4110

On page 1 of the printed A-engrossed bill, line 2, before the period insert "; creating new provisions; and amending ORS 689.522".

On page 2, after line 14, insert:

"SECTION 3. ORS 689.522 is amended to read:

"689.522. (1) As used in this section:

"(a) 'Biological product' means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

"(b) 'Biosimilar product' means a biological product [*licensed by*] **that** the United States Food and Drug Administration**, relying on a reference biological product:**

"(A) Licensed pursuant to 42 U.S.C. 262(k)(3)(A)(i)**; or**

"(B) Approved based on an application filed under 21 U.S.C. 355(b)(2).

"(c) 'Interchangeable' means[,]**:**

"(A) In reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4)**; or**

"(B) In reference to a biological product described in paragraph (b)(B) of this subsection, that the United States Food and Drug Ad-

ministration has designated the product as therapeutically equivalent in the list of approved drug products with therapeutic evaluations.

"(d) 'Reference biological product' means the biological product licensed pursuant to 42 U.S.C. 262(a) **or approved based on an application filed under 21 U.S.C. 355(b)(1)** against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure **or approval** of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

"(2) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

"(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

"(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

"(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product;

"(d) The pharmacy or pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three business days of dispensing the biosimilar product; and

"(e) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

"(3) The State Board of Pharmacy shall post and regularly update on a website maintained by the board a list of biosimilar products determined by the United States Food and Drug Administration to be interchangeable.

"SECTION 4. ORS 689.522, as amended by section 4, chapter 342, Oregon Laws 2013, is amended to read:

"689.522. (1) As used in this section:

"(a) 'Biological product' means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

"(b) 'Biosimilar product' means a biological product [*licensed by*] **that** the United States Food and Drug Administration**, relying on a reference biological product:**

"(A) Licensed pursuant to 42 U.S.C. 262(k)(3)(A)(i)**; or**

"(B) Approved based on an application filed under 21 U.S.C. 355(b)(2).

"(c) 'Interchangeable' means[*,*]**:**

"(A) In reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4)**; or**

"(B) In reference to a biological product described in paragraph (b)(B) of this subsection, that the United States Food and Drug Administration has designated the product as therapeutically equivalent in the list of approved drug products with therapeutic evaluations.

"(d) 'Reference biological product' means the biological product licensed pursuant to 42 U.S.C. 262(a) **or approved based on an application filed under 21 U.S.C. 355(b)(1)** against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure **or approval** of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

"(2) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

"(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed

biological product;

"(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

"(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product; and

"(d) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

"(3) The State Board of Pharmacy shall post and regularly update on a website maintained by the board a list of biosimilar products determined by the United States Food and Drug Administration to be interchangeable.".

In line 15, delete "3" and insert "5".
